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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,853	07/26/2001	Takafumi Ueno	12013/58002	7372

26646 7590 04/06/2004

KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,853

Applicant(s)

UENO ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5,7,9-11,13-15, 18,20,22,24,28-29,31,33,38,40-41, and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,5,7,9-11,13-15,18,20,22,24,28,29,31,33,38,40,41 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Ueno *et al*
Priority Date : 26 July 2000

1. The amendment filed 12/12/2003 is acknowledged and entered into the record. Accordingly, claims 1,3,4,6,8,12,16-17,19,21,23,25-27,30,32,34-36,37,39,42, and 44-73 are canceled without prejudice or disclaimer.
2. Claims 2,5,7,9-11,13-15, 18,20,22,24,28-29,31,33,38,40-41, and 43 are pending and examined on the merits.

Claim Rejections Maintained - 35 USC § 103

3. The rejection of claims 2,5,7,9-11,13-15,18,20,22,24,28-29,31,33,38,40-41,and 43 under 35 USC 103(a) as being obvious over Kobayashi *et al* is maintained for the reasons of record. Applicant's arguments are substantially similar to those previously presented in a paper filed 8/11/2003 for the rejection of claims under 35 USC 102(a). Applicant's arguments have been carefully considered but are not found persuasive to overcome the rejections of record. Although it is understood that Kobayashi *et al* do not specifically teach the isolation of mononuclear cells (MNC) from the bone marrow (BM), it is well known in the art and discussed by Kobayashi *et al* that BM comprise "many kinds of immature cells which could differentiate into hematopoietic cells and endothelial progenitor cells" (EPC) (see page 189 last paragraph). It was also well known and taught by Kobayashi *et al* that EPCs derived from CD34-positive mononuclear cells were responsible for the formation of blood vessels. Because the isolation and

administration of BM cells caused the formation of vascular structures/ angiogenesis and bears no difference between what is taught and that being claimed in the instant application, the mode of action would inherently comprise the use of mononuclear cells. Moreover, Kobayashi *et al* teach that others have isolated and have shown that CD34-positive mononuclear cells were able to differentiate into endothelial cells (see Asahara *et al* (Science Feb 1997; 275:964-967) – teach the isolation of CD34-positive mononuclear cells and showed that these cells differentiated into endothelial cells). Therefore, alone the teaching of Kobayashi *et al* provides the skilled artisan with enough motivation and suggestion to isolate mononuclear cells from the BM because it was well established that the mononuclear portion of the BM cells comprised the EPCs (which are the integral cells for the formation of the vascularized tissue) and that this subset of the BM population was enough for the formation of blood vessels via angiogenesis. Furthermore, because the results obtained in the rat ischemic heart model are indicative of potential human results, one of ordinary skill in the art would easily translate the teachings or data from the rat heart model to that of a human. Therefore, the claims are obvious over Kobayashi *et al* in view of the teachings of Asahara *et al*.

Conclusion

4. No claim is allowed.
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/915,853

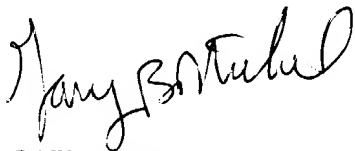
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Art Unit: 1642

Christopher Yaen

Art Unit 1642

March 31, 2004

A handwritten signature in black ink, appearing to read "Gary Nickol". The signature is written in a cursive, flowing style.

GARY NICKOL
PRIMARY EXAMINER